

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| BENTLEY A. HOLLANDER, | : | CIVIL ACTION |
| | : | |
| Plaintiff, | : | |
| | : | |
| v. | : | NO. 2:10-cv-00836-RB |
| | : | |
| ORTHO-McNEIL-JANSSEN | : | |
| PHARMACEUTICALS, INC. | : | |
| | : | |
| Defendant. | : | |

MEMORANDUM

BUCKWALTER, S. J.

October 21, 2010

Presently before the Court is the Motion of Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“Ortho”) to Stay, or in the Alternative, Dismiss the Complaint of Plaintiff Bentley A. Hollander (“Hollander”) pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). For the following reasons, the Court denies the Motion to Stay and grants the Motion to Dismiss.

I. FACTUAL AND PROCEDURAL BACKGROUND

On March 1, 2010, Plaintiff/Relator Bentley A. Hollander, a resident of Philadelphia, Pennsylvania, commenced this *qui tam* action on behalf of the United States against Defendant Ortho, a pharmaceutical company headquartered in New Jersey, for violations of the federal false marking statute, 35 U.S.C. § 292(a). According to the facts alleged in the Complaint, Ortho is a sophisticated global healthcare products business with annual sales of hundreds of millions of dollars. (Compl. ¶ 9, 11.) Defendant Ortho manufactures and sells many products throughout

the United States and “claims to own or have licenses under a substantial number of patents or patent applications.” (Id. ¶¶ 10, 13.)

According to Plaintiff, Defendant Ortho has “repeatedly and knowingly . . . injured the sovereign interests of the United States” and “discouraged or deterred honest competition and innovation” by marking units of its prescription drug products with expired patents.¹ (Id. ¶¶ 2, 39.) Plaintiff further alleges that Defendant is falsely marking its products with “the purpose of deceiving the public into believing that the products were covered by valid patents when, in fact, such patents had expired.” (Id. ¶¶ 2, 38.) Plaintiff’s Complaint brings thirty-nine counts of false marking against Defendant (id. ¶¶ 41-274) and seeks up to a \$500 fine per violation, one half of which is to be paid to the United States pursuant 25 U.S.C. § 292(b). (Id. at Prayer for Relief.) On May 18, 2010, Defendant moved to stay the case pending resolution of two cases in the Federal Circuit, or in the alternative, to dismiss based on Plaintiff’s insufficient standing and inadequate pleadings. Plaintiff filed a Response on June 1, 2010. Defendant submitted a Reply Brief on June 8, 2010, and Plaintiff filed a Sur-Reply on June 11, 2010. Defendant filed a Response on June 16, 2010, and a Notice of Supplemental Authority on August 12, 2010. The Court now turns to a discussion of the Motion to Stay, or in the Alternative, Dismiss.

II. MOTION TO STAY

As an initial matter, the Court denies Defendant’s Motion to Stay. Defendant requested the stay pending the Federal Circuit’s rulings in Pequignot v. Solo Cup Co., 608 F.3d 1356 (Fed.

¹ These products include varying forms and dosages of Risperdone, allegedly marked with U.S. Patent No. 4,804,663 (expiration: Dec. 29, 2007); Nizoral, No. 4,335,125 (exp. June 15, 2000); Terconazole, No.D279, 504 (exp. Jul. 2, 1999); Ofloxacin, No. 4,382,892 (exp. Sept. 2, 2003); and Razadyne, No. 4,663,318 (exp. Dec. 14, 2008).

Cir. 2010) and Stauffer v. Brooks Brothers, Inc., Nos. CIV.A.2009-1428, 2009-1430, 2009-1453, 2010 WL 3397419 (Fed. Cir. Aug. 31, 2010). The Federal Circuit has since ruled on both cases. Accordingly, the Motion is denied.

III. MOTION TO DISMISS

A. STANDARD OF REVIEW

Under Rule 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. FED. R. CIV. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). In Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), the United States Supreme Court recognized that “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Id. at 555. The Court emphasized that it would not require a “heightened fact pleading of specifics,” but only “enough facts to state a claim to relief that is plausible on its face.” Id. at 570.

In the subsequent case of Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009), the Court enunciated two fundamental principles applicable to a court’s review of a motion to dismiss for failure to state a claim. First, it noted that “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. at 1949. Thus, although “[Federal] Rule [of Civil Procedure] 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era . . . it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.” Id. at 1950. Second, the Supreme Court emphasized that “only a complaint that states a plausible claim for relief survives

a motion to dismiss.” Id. The task of determining whether a complaint states a plausible claim for relief is “context-specific,” and “requires the reviewing court to draw on its judicial experience and common sense.” Id. The Supreme Court explained:

The plausibility standard is not akin to a “probability requirement,” but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are “merely consistent with” a defendant’s liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’”

Id. at 1949 (citing Twombly, 550 U.S. at 556-57).

Expanding on the Twombly/Iqbal standards, the United States Court of Appeals for the Third Circuit succinctly defined a two-prong analysis to be undertaken by district courts during a Rule 12(b)(6) review:

First, the factual and legal elements of a claim should be separated. The district court must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions. Second, a district court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a “plausible claim for relief.” In other words, a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to show such an entitlement with its facts. As the Supreme Court instructed in Iqbal, where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not shown—that the pleader is entitled to relief.

Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009) (internal citations omitted).

Notwithstanding the foregoing, many of the fundamental underpinnings of Rule 12(b)(6) still stand. Arner v. PGT Trucking, Inc., No. CIV.A.09-565, 2010 WL 1052953, at *2 (W.D. Pa. Mar. 22, 2010); Spence v. Brownsville Area Sch. Dist., No. CIV.A.08-626, 2008 WL 2779079, at *2 (W.D. Pa. Jul. 15, 2008). Federal Rule of Civil Procedure 8 requires only a short and plain statement of the claim showing that the pleader is entitled to relief and need not contain detailed

factual allegations. FED. R. CIV. P. 8; Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008). Further, the court must “accept all factual allegations in the complaint as true and view them in the light most favorable to the plaintiff.” Buck v. Hampton Twp. Sch. Dist., 452 F.3d 256, 260 (3d Cir. 2006). Finally, the court must “determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” Pinkerton v. Roche Holdings Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002).²

B. DISCUSSION

1. Whether Plaintiff Has Standing to Bring a 35 U.S.C. § 292(a) Claim

Defendant first argues that Plaintiff lacks standing to bring a suit under § 292(a) because he has alleged no concrete injury to himself, the public, or the United States government. (Def.’s Mot. Dismiss 9.) To establish standing under Article III, a plaintiff must show:

(1) that he has suffered an ‘injury in fact,’ an invasion of a legally protected interest that is ‘(a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical,’ (2) that there is ‘a causal connection between the injury and the conduct

² Defendant also moves for dismissal pursuant to Federal Rule of Civil Procedure 12(b)(1). Under 12(b)(1), the Court must dismiss a complaint when it lacks subject matter jurisdiction over an action. FED.R.CIV.P. 12(b)(1). There are two types of Rule 12(b)(1) challenges – facial and factual. Turicentro, S.A. v. Am. Airlines, Inc., 303 F.3d 293, 300 (3d Cir. 2002); Nelson v. Commw. of Pa. Dept. of Pub. Welfare, 244 F. Supp. 2d 382, 386 (E.D. Pa. 2002). In a facial attack on subject matter jurisdiction, the moving party challenges the Court’s jurisdiction based solely on the complaint, and “the court must accept the complaint’s allegations as true.” Turicentro, 303 F.3d at 300. “In contrast, a trial court considering a factual attack accords plaintiff’s allegations no presumption of truth. . . . [and] must weigh the evidence relating to jurisdiction, with discretion to allow affidavits, documents, and even limited evidentiary hearings.” Id.

In the instant action, Defendant makes no specific argument as to subject matter jurisdiction; rather, Defendant challenges Plaintiff’s standing and the factual sufficiency of Plaintiff’s pleadings. Accordingly, Defendant’s challenge is facial, and the Court will accept all of Plaintiff’s allegations as true when determining whether or not the Court has subject matter jurisdiction over the case.

complained of,’ and (3) that the injury is likely to be redressed by a favorable decision. Stauffer, 2010 WL 3397419, at *3 (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992) (citations and quotations omitted)); Vermont Agency v. U.S. ex rel Stevens, 529 U.S. 765, 771 (2000).

Plaintiff need not allege injury to himself or to Defendant’s competitors to establish standing, however. Section 292(b) states that “[a]ny person” may bring suit for a false marking offense, “in which event one-half [of the penalty] shall go to the person suing and the other to the use of the United States.” 35 U.S.C.A. § 292(b) (emphasis added). This *qui tam* provision “operates as a statutory assignment of the United States’ rights,” meaning that the plaintiff, as assignee, “has standing to assert the injury in fact suffered by the assignor.” Stauffer, 2010 WL 3397419, at *4 (citing Vermont Agency, 529 U.S. at 774). Thus, “injury to the United States is sufficient to confer standing” upon plaintiffs, regardless of whether they have suffered personal harm. Simonian v. Cisco Sys., No. CIV.A.10-1306, 2010 WL 2523211, at *2 (N.D. Ill. June 17, 2002) (citing Vermont Agency, 529 U.S. at 773-74).

In the instant case, Plaintiff asserts that Defendant’s alleged violation of § 292 “has injured the sovereign interests of the United States and has discouraged or deterred honest competition and innovation.” (Compl. ¶ 39.) In response, Defendant cites Stauffer v. Brooks Brothers, 615 F. Supp. 2d 248 (S.D.N.Y. 2009) for the proposition that allegations of sovereign harm are too abstract to constitute a cognizable injury.³ The Federal Circuit recently reversed Stauffer, however, finding not only that a violation of § 292 constitutes an “injury in fact” to the

³ Defendant based its Motion to Stay, in part, on the appeal of Stauffer still pending in the Federal Circuit at the time of Defendant’s last filing.

sovereignty of the United States, but that such injury is sufficient to confer standing on *qui tam* plaintiffs. Stauffer, 2010 WL 3397419, at *4. As the court reasoned, “[b]ecause the government would have standing to enforce its own law, Stauffer, as the government’s assignee, also has standing to enforce section 292.” Id. In light of the Federal Circuit’s ruling in Stauffer, the Court finds that Plaintiff Hollander has standing to bring a *qui tam* action on behalf of the United States. Plaintiff’s standing arises from his status as “any person” within the meaning of § 292(b), and his allegations of harm to the sovereign interests of the United States stemming from alleged violations of § 292. Accordingly, the Court declines to grant Defendant’s Motion to Dismiss on the basis of standing.

2. Whether Plaintiff Has Sufficiently Pleaded a 25 U.S.C. § 292 Claim

Defendant next contends that Plaintiff has failed to state a plausible claim under the pleading standards of Federal Rules of Civil Procedure 8 and 9(b). Specifically, Defendant argues that Plaintiff has failed to allege facts showing Defendant’s intent to deceive the public as required by § 292.

To state a false marking claim under § 292, a plaintiff must show “(1) a marking importing that the article is patented (2) falsely affixed to (3) an unpatented article (4) with the intent to deceive the public. Brinkmeier v. Graco Children’s Prods., 684 F. Supp. 2d 548, 551 (D. Del. 2010) (citing Clontech Labs., Inc. v. Invitrogen Corp., 406 F.3d 1347, 1352 (Fed. Cir. 2005); Juniper Networks v. Shipley, No. CIV.A.09-0696, 2009 WL 1381873, at *3 (N.D. Cal. May 14, 2009)). Although the Federal Circuit has yet to address whether § 292’s required showing of deceptive intent invokes the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), Third Circuit courts have agreed that it does. See Hollander v. Etymotic

Research, Inc., No. CIV.A.10-526, 2010 WL 2813015, at *7 (E.D. Pa. Jul. 14, 2010) (“The Court is persuaded by the law of other district courts holding that false marking claims are fraud-based claims subject to Rule 9(b)’s heightened pleading standards.”); Brinkmeier v. BIC Corp., Nos. CIV.A. 09-860-SLR, 10-01-SLR, 2010 WL 3360568, at *8 (D. Del. Aug. 25, 2010) (“BIC”) (“The court agrees with the United States District Court for the Eastern District of Pennsylvania, and other districts, that the heightened pleading standard of Rule 9(b) applies to section 292 claims.”); see also Exergen v. Wal-mart Stores, Inc., 575 F.3d 1312, 1330-31 (Fed. Cir. 2009) (finding that Rule 9(b) standards apply to inequitable conduct claims, which also require a showing of intent to deceive). Courts have noted, however, that “a relaxed Rule 9(b) standard may apply ‘when essential information lies uniquely within another party’s control.’” BIC, 2010 WL 33605678, at *5 (citing Exergen, 575 F.3d at 1330-31; In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997)). As a result, “a plaintiff may plead based upon information and belief, ‘but only if the pleading sets forth specific facts upon which the belief is reasonably based.’” Id. Courts have emphasized that “boilerplate and conclusory allegations will not suffice.” BIC, 2010 WL 33605678, at *5 (citing Burlington, 114 F.3d at 1418). Instead, plaintiffs must offer “factual allegations that make their theoretically viable claim plausible.” Id.

Here, Plaintiff alleges, “on information and belief,” that Defendant “has repeatedly and knowingly violated 35 U.S.C. § 292(a) by falsely marking numerous units of its products for the purpose of deceiving the public into believing that the products were covered by valid patents when, in fact, such patents had expired.” (Compl. ¶¶ 2, 10.) In support of these claims, Plaintiff alleges that Defendant is a “highly sophisticated business entity” with “extensive experience with the application for, procurement of, and publication of its patents” (id. ¶ 12); that Defendant “has

marked and continues to mark many of its products with expired patents (id. ¶ 38); and that Defendant, based on its experience with the patent process, “knows or reasonably should know that it is falsely marking its [] products with an expired patent.” (Id. ¶ 20.)

Defendant argues for dismissal of Plaintiff’s claim based on Plaintiff’s failure to offer any facts supporting his allegations of deceptive purpose on the part of Defendant. (Def.’s Mot. Dismiss 16-17.) The Court agrees. Even under a relaxed 9(b) standard, a plaintiff must allege sufficient underlying facts from which a court may reasonably infer that the defendant intended to deceive the public. BIC, 2010 WL 33605678, at *5 (citing Burlington, 114 F.3d at 1418). In a nearly identical action recently brought by the same Plaintiff in front of another court of the Eastern District of Pennsylvania, the court dismissed Plaintiff’s claim based on his failure to allege “specific facts showing Defendant’s knowledge of falsity or intent to deceive.” Hollander, 2010 WL 2813015, at *6.

Although Plaintiff has alleged that Defendant knew or reasonably should have known that the products were marked with expired patents, Plaintiff attempts to support these obligations by averring merely that: (1) Defendant knows the patents have limited duration; (2) the patents at issue expired; and (3) Defendant continued to mark its products with those patents after expiration. Those allegations do not sufficiently articulate knowledge of falsity or intent to deceive because Defendant’s knowledge of the limited duration of patents and the actual expiration of the patents do not create an inference that Defendant knew that the patents at issue actually expired. Moreover, Plaintiff’s allegations based on information and belief are insufficient under Rule 9(b) where Plaintiff has failed to set forth specific facts upon which such belief is reasonably based. Therefore, Plaintiff’s allegations do not meet Rule 9(b)’s heightened pleading standards.

Id.

Similarly, in Brinkmeier v. Graco, 684 F. Supp. 2d at 553, a district court within the Third Circuit found that allegations that the defendant merely knew or should know that the

products were falsely marked, and that the defendant marked the products with expired patents “for the purpose of deceiving the public” did not, on their own, “supply enough factual matter to suggest an intent to deceive.” Indeed, the court found such allegations insufficient to fulfill even the liberal pleading standards of 8(a). *Id.* By way of contrast, the court found that the plaintiff *had* sufficiently pled intent to deceive with respect to two other false marking claims. For those claims, the plaintiff supported its allegations by averring that the defendant had been sued by two competitors for infringing the same patent and had revised its patent markings multiple times since the patents had expired. *Id.*

In the case at bar, Plaintiff offers no such factual support for Defendant’s alleged knowledge of falsity or intent to deceive. Accordingly, the Court finds that Plaintiff has failed to allege the intent necessary to assert a plausible claim under the heightened pleading standards of Rule 9(b), and therefore grants Defendant’s Motion to Dismiss on these grounds.⁴

IV. CONCLUSION

For the foregoing reasons, the Court denies Defendant’s Motion to Stay and grants the Motion to Dismiss. The dismissal of this action is without prejudice, and the Court grants Plaintiff leave to submit an amended complaint on or before November 22, 2010.

An appropriate order follows.

⁴ The Court notes that Defendant has also moved to dismiss Plaintiff’s Complaint based on the proposition that an expired patent does not constitute an “unpatented” article within the meaning 35 U.S.C. § 292(a), and that some of the products in question are still covered under valid patents. The Court declines to address these issues based on its dismissal of the claim on other grounds.